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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,583	07/31/2001	Charles L. Truwit	1276.004US1	2602

7590 05/22/2003
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EXAMINER

WEBB, SARAH K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 05/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

GL

Office Action Summary	Application No.	Applicant(s)	
	09/919,583	TRUWIT ET AL.	
	Examiner	Art Unit	
	Sarah K Webb	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-13 and 17-33 is/are pending in the application.
- 4a) Of the above claim(s) 23-25,32, and 33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-31 is/are allowed.
- 6) ☒ Claim(s) 1-5,9-13 and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 23-25, 32, and 33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

- New claims 23-25 are directed toward the species illustrated in Figure 1
- New claims 32 and 33 are directed toward the species illustrated in Figures 4 and 5, which has a rotating inner member.

Since applicant has received an action on the merits for the originally presented invention, which is illustrated in Figures 2 and 3, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 23-25, 32, and 33 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 states “the cylindrical member” in lines 2 and 4. It is unclear whether applicant is referring to the *introducer* or *inner* member, because both members are *cylindrical*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1,9, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,027,514 to Stine et al.

Stine discloses a device that includes an introducer member (20) and an inner member (22), as shown in Figures 3A-D and 4A-D. Both members have openings (46) along a side, and both openings have cutting means (60). As shown in Figures 4A-4D, tissue (M) enters both openings, and the members are moved relative to each other without rotating to cut the tissue. One can interpret this movement in two ways: 1) the inner moves with respect to the introducer; 2) the introducer is moved relative to the inner member.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-5 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,527,331 to Kresch et al.

Regarding the independent claims 1,9: Kresch discloses a tissue cutting and electrocautery device. Referring to Figure 2A, an introducer member (P) is provided with an opening (18) along a side and an electrocautery cutting head (C) positioned within the member (P). Figure 6B shows an alternate cutting head (C) that is in the form of a wire. The embodiment in Figure 2A meets the limitations of claim 1, but the cutting means does not travel *without rotating*. Kresch illustrates another type of electrocautery cutting wire (202) that can travel in a linear manner with respect to the delivery member (column 13, lines 54-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the cutting wire of Figure 6B so that it translates relative to the delivery member without rotating, as Kresch teaches in another embodiment that an electrocautery cutting wire can function if moved only in a linear direction.

Regarding claims 2,5,10,13: In lines 45-48 of column 7, Kresch explains the cutting means also operates to coagulate blood. This means that cautery results immediately after or simultaneously as the cutting heads passes over flesh.

Regarding claims 4,12: An ultrasonic transducer (T) is connected to the cutting head (C), which could be configured to facilitate cutting or coagulation.

Referring to claims 9-13: Kresch describes the method in which the tissue resection device is used during operation beginning in line 66 of column 3. Figure 14 illustrates operation of one embodiment. The method includes positioning the device within the body, translating the

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electrosurgical wire relative to the outer shaft to cut tissue, cauterizing tissue, and using ultrasonic energy to aid in the procedure.

Response to Arguments

5. Applicant's arguments with respect to claims 1-5, 9-13 have been considered but are moot in view of the new ground(s) of rejection.

6. Applicant's arguments, see Amendment A, filed 3/18/03, with respect to the rejection(s) of claim(s) 17 under 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Stine.

Allowable Subject Matter

7. Claims 26-31 are allowed. The following is a statement of reasons for the indication of allowable subject matter: Prior art discloses many tissue cutting devices that utilize electrocautery. Prior art fails to disclose a device with a cutting wire at one end of a side opening in an inner tubular member, where the cutting wire traverses a side opening in an outer tubular member.

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Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Sarah K Webb
Examiner
Art Unit 3731

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May 15, 2003


Michael Milano
Supervisory Patent Examiner
Art Unit 3731